UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

CLARKSON S. FISHER FEDERAL
BUILDING & U.S. COURTHOUSE
402 EAST STATE STREET
TRENTON, N.J. 08608
609-989-2009

NOT FOR PUBLICATION

February 26, 2021

LETTER OPINION

VIA CM/ECF
All counsel of record

Re: *Randy Smith v. Antares Pharma, Inc., et al.*,
Civil Action No. 17-8945 (MAS) (DEA)

Dear Counsel:

This matter comes before the Court upon Defendants Antares Pharma, Inc.'s ("Antares" or the "Company"), Robert Apple, Fred Powell, and Leonard Jacob's (collectively, "Defendants") Motion to Dismiss the Consolidated Third Amended Class Action Complaint. (ECF No. 72.) Lead Plaintiff Serghei Lungu ("Plaintiff") opposed (ECF No. 76) and Defendants replied (ECF No. 78). The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth herein, Defendants' Motion is granted.

I. Background

The parties are familiar with the factual and procedural history of this matter, and therefore the Court only recites those facts necessary to resolve the instant motion. Plaintiff seeks to represent a class of persons who purchased Antares common stock between December 21, 2016 and October 12, 2017, both dates inclusive (the "Class Period"). (Cons. Third Am. Class Action Compl. ("TAC") ¶ 1, ECF No. 66.) Antares is a company that develops, manufactures, and commercializes therapeutic products using drug delivery systems. (*Id.* ¶¶ 2-3.) The non-Company Defendants were executives at Antares during the Class Period. (*See id.* ¶¶ 27-29, 122.)

This action principally arises from statements that Defendants allegedly made during the Class Period. Plaintiff alleges that Defendants misled investors by downplaying and misstating the incidence of certain adverse events[1]—hypertension, suicidality, and depression—observed in two Phase 3 clinical studies[2] of Antares's lead product, QuickShot Testosterone ("QST"). (*Id.*

[1] "Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 312.32.

[2] Phase 3 studies "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and

¶ 7.) QST is an auto-injector product designed for testosterone replacement therapy. (*Id.* ¶ 4.) It is currently approved by the Food and Drug Administration ("FDA") and marketed as Xyosted. (*Id.* ¶¶ 4, 167.)

According to Plaintiff, "[u]nbeknownst to investors throughout the Class Period, but known at all relevant times within the Company, the incipient [QST] [New Drug Application ("NDA")] was facing serious risks in regard to (a) the clinically meaningful increase noted in blood pressure (i.e., hypertension); and (b) the instance of suicidality [and] depression." (*Id.* ¶ 97.) Defendants allegedly knew of QST's hypertension risk, "yet consciously sought to downplay its significance instead of disclosing the direct link between QST and elevated blood pressure that the FDA would ultimately force the Company to acknowledge." (*Id.* ¶ 102.) Defendants are also alleged to have inaccurately reported the instances of suicide and depression. (*Id.* ¶ 105.) Plaintiff alleges that Antares, accordingly, "overstated the approval prospects for [QST]," (*id.* ¶¶ 136, 139, 143, 145, 147, 150, 156), and artificially inflated Antares share prices (*id.* ¶¶ 25, 188, 192-93).

In a previous complaint, Plaintiff challenged eight instances in which Defendants allegedly made false or misleading statements in violation of Rule 10b–5 and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). *Smith v. Antares Pharma, Inc.*, No. 17-8945, 2020 WL 2041752, at *4 (D.N.J. Apr. 28, 2020). These included: (1) a press release dated December 21, 2016; (2) a press release dated February 27, 2017; (3) a form 10-K dated March 14, 2017; (4) a press release dated April 3, 2017; (5) a conference call on May 9, 2017; (6) a form 10-Q dated May 9, 2017; (7) a conference call on August 8, 2017; and (8) a form 10-Q dated August 8, 2017. *Id.*

After considering the Second Amended Complaint's ("SAC") allegations regarding these statements, the Court found that Plaintiff's Section 10(b) claims failed for a variety of reasons. For example, the Court found that Plaintiff "fail[ed] to plead economic loss and loss causation. It is not enough to allege an 'artificially inflated purchase price' as an economic loss." *Id.* at *10 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). The Court also found that Plaintiff failed to plead facts that gave rise to a strong inference of scienter with respect to the foregoing statements. *Id.* at *8-9. Additionally, the Court found that for all but one of these statements, Plaintiff failed to adequately plead facts showing that they were false or misleading for the purposes of Section 10(b) and Rule 10b–5 liability. *Id.* at *5-7.[3] Nevertheless, the Court found that even if Plaintiff had adequately alleged that any of these statements were false or misleading, Plaintiff had failed to plead facts showing that these statements were material. (*Id.* at *7-8.) Finally, the April 28, 2020 Opinion also dismissed Plaintiff's Section 20(a) claims because

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safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c).

[3] The SAC cited "Apple's statement during the August 8, 2017 conference call that 'anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for Xyosted.'" *Id.* at *7 (quoting SAC ¶ 145, ECF No. 46) "Apple also stated, 'I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate.'" *Id.* (quoting SAC ¶ 146). The Court found "that these statements could be misleading considering hypersensitive patients are excluded from" one of the relevant studies. *Id.*

Section 20(a) liability is predicated on successfully pled Section 10(b) claims. *Id.* at *10 (citing *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013)).

Although the Court dismissed Plaintiff's Second Amended Complaint, Plaintiff was granted leave to file a Third Amended Complaint.[4] (ECF No. 65.) Plaintiff's Third Amended Complaint is virtually identical to the Second Amended Complaint. (*See generally* TAC; Redline, Ex. 1 to Defs.' Mot. to Dismiss, ECF No. 72-3.)

The Third Amended Complaint does, however, add new allegations relating to the scienter element of Plaintiff's Section 10(b) claim. According to Plaintiff, a confidential witness, CW2, who was the director of Quality Assurance for Antares from November 2012 to June 2017, alleges that "everyone at the Company knew about the safety issues with Xyosted because they had to postpone the launch and do an additional safety study (QST-15-005)." (TAC ¶ 121.) According to CW2, "[t]here were only twenty-five (25) to thirty (30) employees at the Ewing headquarters, making it so it would have been impossible for CEO Apple and CFO Powell[] not to know about the safety issues that ultimately resulted in boxed warning." (*Id.*) Furthermore, CW2 alleges that "when company employees started hearing about Phase 3 clinical trial-patients having elevated blood pressure, committing suicide, and exacerbating depression, they discussed those issues at the regular, weekly meetings" held by CW2's team. (*Id.* ¶¶ 129-30.) Plaintiff also alleges that "for the second, six-month study (QST-15-005), monitoring devices for blood pressure were used so if someone tested high, they were not allowed into the study, and questions about depression [were] included in the questionnaire to exclude anyone with a history of depression." (*Id.* ¶ 132.)

Moreover, although the SAC previously challenged certain statements in the December 21, 2016 and February 27, 2017 press releases, (*see* SAC ¶¶ 128, 131), the TAC takes issue with additional statements contained within these documents. In the now-operative TAC, Plaintiff asserts that in the December 21, 2016 press release, "Defendant Apple further claimed that another 'benefit to patients is a virtually painless treatment experience as demonstrated by the pain data collected in our phase 3 program.'" (TAC ¶ 134). "We will work closely with the FDA during the regulatory review process towards a potential approval with the goal of bringing this new treatment option to men diagnosed with hypogonadism." (*Id.*) With respect to the February 27, 2017 press release, "[t]he company further stated that 'the study data also showed patients had a virtually painless treatment experience using the device. We will work closely with the FDA during the regulatory review process toward a potential approval.'" (*Id.* ¶ 137).

II. Legal Standard

A district court must conduct a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *See Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The Court must take note of the elements a plaintiff must plead to state a claim; review the complaint to strike conclusory allegations; and accept as true all of the plaintiff's well-pled factual allegations while "construe[ing] the complaint in the light most favorable to the

[4] The Second Amended Complaint was itself filed after the Court dismissed an even earlier complaint that failed to adequately plead securities fraud. *See Smith v. Antares Pharma, Inc.*, No. 17-8945, 2019 WL 2785600, at *11 (D.N.J. July 2, 2019).

plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). The Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A facially plausible claim "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678).

Because Plaintiff alleges fraud, Plaintiff "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The Private Securities Litigation Reform Act ("PSLRA") also imposes a heightened standard "to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

III. Discussion

A plaintiff bringing an action under Section 10(b) and Rule 10b–5 must plead: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx, Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011) (quoting *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). "[T]he PSLRA imposes greater particularity requirements concerning alleged material misrepresentations and scienter." *Fan v. StoneMor Partners LP*, 927 F.3d 710, 714 (3d Cir. 2019).

A. The TAC's New Factual Assertions Relating to Falsity and Materiality

The Court finds that Plaintiff's new factual assertions regarding QST's "virtually painless treatment experience" fail to support the falsity or materiality elements of Section 10(b) liability.

"[Section] 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)). "[Defendants'] statements are only actionable if, when read in light of all the information then available to the market or a failure to disclose particular information, [Defendants] conveyed a false or misleading impression." *Fan*, 927 F.3d at 715 (internal citations and quotation marks omitted). Under the PSLRA, a complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation . . . is made on information and belief, . . . state with particularity all facts on which that belief is formed." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 166 (3d Cir. 2014) (quoting 15 U.S.C. § 78u–4(b)(1)(B)).

"Interpretations of clinical trial data are considered opinions. Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *Edinburgh*, 754 F.3d at 170 (internal citations omitted). A company's press release releasing "positive" study results is not misleading where the plaintiff fails to allege that the opinion lacked a reasonable basis. *See, e.g.*, *Biondolillo v. Roche Holding Ag.*, No. 17-4056, 2018 WL 4562464, at *5 (D.N.J. Sept. 24, 2018); *cf. In re Merck & Co., Sec., Derivative, & ERISA Litig.*, 2011 WL 3444199, at

*15 (D.N.J. Aug. 8, 2011) (finding alleged facts showed the company had no reasonable basis for and disbelieved its public characterization of the study results).

Furthermore, Plaintiff must plead that Defendants' statements were "misleading as to a material fact." *Matrixx*, 563 U.S. at 38. "[T]o fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)) (internal quotation marks omitted); *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 283 (3d Cir. 2010).

"Assessing the materiality of adverse event reports is a fact-specific inquiry that requires consideration of the source, content, and context of the reports." *Matrixx*, 563 U.S. at 43 (internal citation and quotation marks omitted). Nevertheless, "complaints alleging securities fraud often contain claims of omissions or misstatements that are obviously so unimportant that courts can rule them immaterial as a matter of law at the pleading stage." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). Relatedly, "[m]aterial representations must be contrasted with statements of subjective analysis or extrapolations, such as opinions, motives[,] and intentions, or general statements of optimism[.]" *Aetna*, 617 F.3d at 283 (citation omitted). "[V]ague and general statements of optimism . . . are not material [because] a reasonable investor would not base decisions on such statements." *Fan*, 927 F.3d at 716.

Just as the SAC challenged statements in the December 21, 2016 and February 27, 2017 press releases, the TAC again challenges statements in these documents. *See Smith*, 2020 WL 2041752, at *5. In the now-operative TAC, Plaintiff asserts that in the December 21, 2016 press release, "Defendant Apple further claimed that another 'benefit to patients is a virtually painless treatment experience as demonstrated by the pain data collected in our phase 3 program." (TAC ¶ 134). Similarly, with respect to the February 27, 2017 press release, "[t]he company further stated that 'the study data also showed patients had a virtually painless treatment experience using the device.'" (*Id.* ¶ 137).

Plaintiff argues that these statements reporting study results were false or misleading in light of Defendants' knowledge of adverse events related to hypertension and suicide. Here, the press releases offer interpretations of the clinical trial data and are considered opinions. *See Edinburgh*, 754 F.3d at 170. But because Plaintiff fails to plead facts that show that Defendants did not have a reasonable basis for their opinions that QST was "virtually painless," Plaintiff has not demonstrated that these statements are actionable. With respect to materiality, as Defendants persuasively argue, "[a]ny reasonable investor would understand this statement to be a commentary on injection pain—not safety or adverse events." (Defs.' Moving Br. 25, ECF No. 71-1 (citations omitted).)

B. The TAC's New Factual Assertions Relating to Scienter

CW2's allegations do not establish that any of the Defendants' challenged statements were made with the scienter necessary to establish Section 10(b) violations. Scienter is "a mental state embracing intent to deceive, manipulate, or defraud," *Matrixx*, 563 U.S. at 48 (citing *Tellabs*, 551

U.S. at 319), or encompassing reckless or conscious behavior, *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 267 (3d Cir. 2009). To plead a "knowing or reckless state of mind" in the securities context, Plaintiff must plead "an extreme departure from the standards of ordinary care." *Id.* at 252, 267 n.42.

"[T]he plaintiff's pleadings [must] conjure a 'strong inference' that the defendant[s] acted with the . . . intent to defraud shareholders." *Fan*, 927 F.3d at 717-18 (quoting 15 U.S.C. § 78u-4(b)(2)(A)). A court "must analyze the complaint holistically" and "not whether any individual allegation, scrutinized in isolation, meets that standard." *In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018) (quoting *Tellabs*, 551 U.S. at 323). A plaintiff only clears the high hurdle imposed by the PSLRA if "a reasonable person [would] deem the inference of scienter at least as strong as any opposing inference." *Tellabs*, 551 U.S. at 326.

CW2 alleges that Defendants were aware of risks to patients using QST because, "for the second, six-month study (QST-15-005), monitoring devices for blood pressure were used so if someone tested high, they were not allowed into the study, and questions about depression [were] included in the questionnaire to exclude anyone with a history of depression." (TAC ¶ 132.) But the Court has already considered and rejected similar allegations in the SAC. (*See, e.g.*, SAC ¶ 147 ("Defendants had themselves excluded patients with high blood pressure from QST-15-005").) And as Plaintiff pleads in the TAC, "Antares finalized and submitted the [005 Study] protocol . . . and enrolled patients [in the study] . . . pursuant to the FDA's recommendations." (TAC ¶ 80.) As the Court previously held when considering similar allegations in the SAC, "[t]he FDA, therefore, approved the study design and would presumably approve QST on the data from this study. Indeed, QST was ultimately approved, albeit with a black box warning and an additional warning and precaution. The exclusion of certain patients from the 005 Study does not, therefore, support a finding of scienter," where the exclusion was done on the FDA's recommendation. *Smith*, 2020 WL 2041752, at *9.

CW2's allegation that "everyone at the Company knew about the safety issues with Xyosted because they had to postpone the launch and do an additional safety study (QST-15-005)" is similarly unavailing. (TAC ¶ 121.) According to CW2, "[t]here were only twenty-five (25) to thirty (30) employees at the Ewing headquarters, making it so it would have been impossible for CEO Apple and CFO Powell[] not to know about the safety issues that ultimately resulted in boxed warning." (*Id.*) Here, as in prior opinions, "the Court steeply discount[s] [the confidential witness's] allegations for failing to satisfy the PSLRA's stringent pleading requirements." *Smith*, 2020 WL 2041752, at *2 n.5; *Smith v. Antares Pharma, Inc.*, No. 17-8945, 2019 WL 2785600. at *8-9 (D.N.J. July 2, 2019). Such generalized, conclusory allegations do not plead particularized facts that give rise to a strong inference of scienter. *Edinburgh*, 754 F.3d at 166 (citing 15 U.S.C. § 78u–4(b)(1)(B)) (requiring plaintiffs to "plead the who, what, when, where, and how: the first paragraph of any newspaper story").

CW2 also suggests that the Defendants had knowledge of the adverse events because sometime after July 2014, "when company employees started hearing about Phase 3 clinical trial-patients having elevated blood pressure, committing suicide, and exacerbating depression, they discussed those issues at the regular, weekly meetings" held by CW2's team. (TAC ¶¶ 129-30.) But these allegations are also insufficient to establish a strong inference of scienter. Similar to the

allegations by CW1 dismissed in an earlier opinion, CW2's allegations about who, what, when, and how the Defendants knew about the adverse events are "ambiguous." *Smith*, 2020 WL 2041752, at *2 n.5, 9 (citations omitted). Once again, "Plaintiff does not allege that the FDA thought or communicated to Defendants [that] the occurrence of adverse events threatened or would delay QST's approval. To the contrary, the alleged facts suggest that Antares informed investors of the delay in approval immediately after receiving the FDA's October 11, [2017] Letter." *Id.* at *9 (citations omitted). Nor do Plaintiff or CW2 allege that Defendants "believed the occurrence of these adverse effects rendered QST unsafe or would negatively affect QST's approval prospects." *Id.* at * 2 n.5.

C. The Previous Factual Allegations Brought in the SAC and Reasserted in the TAC

The TAC reasserts that the eight statements previously rejected by the Court violated Section 10(b). (*Compare* TAC ¶¶ 134-56, *with* SAC ¶¶ 128-50.) As Defendants correctly argue, however, the Court has already examined each of these statements and held that Plaintiff failed to satisfy the elements of a Section 10(b) claim. Previously, those claims failed because Plaintiff failed to plead facts demonstrating economic loss, loss causation, scienter, materiality, and falsity. *Smith*, 2020 WL 2041752, at * 6-10. For the reasons set forth above, Plaintiff's new allegations regarding scienter do not redeem these claims. And as Defendants note, the TAC makes no effort to redress the SAC's failure to plead economic loss or loss causation. (Defs.' Moving Br. 36-37.)[5] The falsity and materiality deficiencies associated with each of the previously rejected eight statements remain unaddressed. Accordingly, the Court will again dismiss Plaintiff's Section 10(b) claims to the extent that they rely on these eight statements.[6]

IV. Conclusion

For the foregoing reasons, Defendants' Motion to Dismiss is granted. An order consistent with this Letter Opinion will be entered.

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

[5] The Court finds that Plaintiff also fails to plead economic loss and loss causation with respect to the TAC's added factual allegations that Defendants misleadingly described QST as "virtually painless."

[6] Because the TAC fails to plead a Section 10(b) violation, Plaintiff's Section 20(a) claim will be dismissed as well. *See Smith*, 2020 WL 2041752, at *10 (finding that "[l]iability under Section 20(a) 'is derivative of an underlying violation of Section 10(b) by the controlled person'" (quoting *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013))).